This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0009
CUSTOMER NUMBER: 519

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Novartis Pharmaceuticals Corporation
Bldg 437/1329 One Health Plaza
East Hanover, NJ 07936

NOV 25 2005

Telephone: (973) -781-0074

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	57	162	14	7	183
5. Cats	0	0	0	0	0
6. Guinea Pigs	6	0	0	0	0
7. Hamsters	7	0	0	0	0
8. Rabbits	4	519	0	43	562
9. Non-human Primates	181	521	68	28	617
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

DATE SIGNED 11-18-05

(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

USDA ANNUAL REPORT OF RESEARCH FACILITY FOR 2004-2005
NOVARTIS PHARMACEUTICALS CORPORATION
USDA Registration No. 22-R-0009

Summary of the NACUC approved exceptions to the Standards and Regulations:
Canine Exercise Exemptions

Protocol Title	Species	Number	Days Without Exercise	Reason
1. Oral Toxicity	Dogs	2	6	Treat and prevent the spread of Coccidiosis
2. Oral Toxicity	Dogs	2	4	Prescribed rest following a bone marrow biopsy
3. Oral Toxicity	Dogs	2	7	Prescribed rest following a limb sprain
4. Telemetry Device Implantation	Dogs	11	7	Prescribed rest following surgery
5. Drug Metabolism	Dogs	2	7	Radioactive isolation

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 4 . Number of animals classified as category "E" - 2 .

3. Species (common name)____Dog_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These dogs were dosed with a pharmaceutical compound.

   One dog was found dead on study and the other dog experienced four consecutive days of emesis following dosing.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   One dog was found dead without prior signs of pain or distress. The overall clinical condition of the other dog was not deemed so severe that the animal could not continue on the study. Relieving the cause of the emesis could have defeated the purpose of the study.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 3 . Number of animals classified as category "E" - 3 .

3. Species (common name)____Dog_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These dogs were dosed with a pharmaceutical compound.

   Three dogs on study experienced head shaking and ataxia for several hours following dosing.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   The overall clinical condition of the dogs was not deemed so severe that the animals could not continue on the study. Relieving the cause of the ataxia and head shaking would have defeated the purpose of the study.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 4 . Number of animals classified as category "E" - 2 .

3. Species (common name)____Dog_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These dogs were dosed with a pharmaceutical compound.

   Two animals on this study experienced compound related effects of being found in a moribund state and were therefore euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 98 . Number of animals classified as category "E" - 1 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   One animal had an abortion while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   As soon as signs indicating that an animal was experiencing pain or distress were observed the animal was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 30 . Number of animals classified as category "E" - 4 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   Four rabbits were found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   These animals were found dead without prior signs of pain or distress.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 98 . Number of animals classified as category "E" - 8 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   Four animals on this study experienced compound related effects, were found to be moribund and were euthanized. One animal had an abortion while on study. Three other rabbits were found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   As soon as signs indicating that an animal was experiencing pain or distress were observed the animal was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 32 . Number of animals classified as category "E" - 10 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   Ten rabbits were found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   These animals were found dead without prior signs of pain or distress.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 30 . Number of animals classified as category "E" - 8 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   Five animals on this study experienced compound related effects and were euthanized. Three of these five animals were found to be moribund and the other two had abortions. Three other rabbits were found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   As soon as signs indicating that an animal was experiencing pain or distress were observed the animal was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 98 . Number of animals classified as category "E" - 8 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   Four animals on this study experienced compound related effects and were euthanized. Two of these four animals were found to be moribund and the other two had abortions. Four other rabbits were found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   As soon as signs indicating that an animal might be experiencing pain or distress were observed the animal was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 98 . Number of animals classified as category "E" - 4 .

3. Species (common name)____Rabbit_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These rabbits were dosed with a pharmaceutical compound.

   Three rabbits experienced compound related effects and were euthanized. One rabbit was found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   As soon as there were signs indicating that these animals were experiencing pain or distress, euthanasia was performed. The other animal was found dead without prior signs of pain or distress.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

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OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 64 . Number of animals classified as category "E" - 5 .

3. Species (common name)____Marmoset_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These marmosets were dosed with a pharmaceutical compound.

   Five animals on this study experienced compound related effects that resulted in the animals being found in a moribund state.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   These animals were immediately scheduled for humane euthanasia and necropsy after they were found in a moribund condition.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 72 . Number of animals classified as category "E" - 8 .

3. Species (common name)____Marmoset_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These marmosets were dosed with a pharmaceutical compound.

   Seven animals on this study experienced compound related effects that resulted in the animals being found in a moribund state. One additional animal was found dead while on study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   With the exception of the one animal that was found dead, these animals were immediately scheduled for humane euthanasia and necropsy.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

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OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 18 . Number of animals classified as category "E" - 2 .

3. Species (common name)____Cynomolgus Monkey_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These monkeys were dosed with a pharmaceutical compound.

   Two animals on this study experienced compound related effects which lead to the animal being found in a moribund state.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   This animals were immediately scheduled for humane euthanasia and necropsy after being found in a moribund condition.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

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OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 2 . Number of animals classified as category "E" - 1 .

3. Species (common name)____Cynomolgus Monkey_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These monkeys were dosed with a pharmaceutical compound.

   One animal on this study experienced compound related effects which lead to the animal being found in a moribund state.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   This animal was immediately scheduled for humane euthanasia and necropsy.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

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OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 32 . Number of animals classified as category "E" - 6 .

3. Species (common name)____Cynomolgus Monkey_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These monkeys were dosed with a pharmaceutical compound.

   Five animals on this study experienced compound related effects which lead to them being found in a moribund state. One animal was found dead.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   The animals found in a moribund condition were immediately scheduled for humane euthanasia and necropsy. One animal was found dead without showing prior signs of pain or distress.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 10 . Number of animals classified as category "E" - 3 .

3. Species (common name)____Cynomolgus Monkey_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These monkeys were dosed with a pharmaceutical compound.

   Three animals on this study experienced compound related effects which lead to the animals being found in a moribund state.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   These animals were immediately scheduled for humane euthanasia and necropsy.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

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OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 4 . Number of animals classified as category "E" - 1 .

3. Species (common name)____Cynomolgus Monkey_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These monkeys were dosed with a pharmaceutical compound.

   One animal on this study experienced compound related effects such as cyanosis, lethargy and anorexia.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   The overall clinical condition of the animal was not deemed so severe that the animal could not continue on study. Relieving the cause of the clinical signs would have defeated the purpose of the study.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study: 40 . Number of animals classified as category "E" - 2 .

3. Species (common name)____Cynomolgus Monkey_____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   These monkeys were dosed with a pharmaceutical compound.

   One animal on this study experienced compound related effects resulting in the animal passing feces that was 25% diarrhea for more than 7 consecutive days in duration. Another animal had a rectal prolapse that was replaced and did not re-occur.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

   The overall clinical conditions observed were not deemed so severe that the animals could not continue on study. Relieving the cause of the diarrhea would have defeated the purpose of the study.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

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